SUPERIOR COURT RETURN DATE: August 5, 2003

MAREK ZAKRZEWSKI

J.D. OF DANBURY Plaintiff,

AT DANBURY

PURDUE PHARMA

JULY 18, 2003 Defendant.

#### COMPLAINT

COUNT ONE: (Retaliation for Protesting Unsafe Activities-Violation of C.G.S. § 31-51m)

- The Plaintiff, Marek Zakrzewski, PhD, is a person who resides, and at all relevant times, resided in Danbury, Connecticut.
- 2 The Defendant, Purdue Pharma (hereinafter "Purdue"), is a pharmaceutical company with its main headquarters in Stamford, Connecticut.
  - Plaintiff was hired as an Assistant Director by Purdue in July 2000. 3.
- At Purdue, Plaintiff conducted research on Oxycodone HCl, a narcotic used in a pain killer called Oxycontin, which was, and still is, manufactured and produced by Defendant Purdue.
- Beginning in May 2001 and continuing throughout his employment with 5. Purdue, Plaintiff informed management of his discoveries involving Oxycontin and the serious negative implications they could have for consumers.
- 6 Through his research and testing, Plaintiff found that the dissolution speed varied in Oxycodone HCI.
  - 7 The faster dissolving form of Oxycodone HCI was used in uncontrolled

amounts in the production of Oxycontin.

- This faster form could potentially dissolve more quickly into the human body than expected and cause overdosing and potentially lead to addiction
- The license to market Oxycontin was granted by the FDA based on the 9. belief that there was only one form of Oxycodone HCI
- Plaintiff's findings raised serious issues about the rate in which 10 Oxycodone dissolved into the human body and the probability of a user becoming addicted.
- 11 Management forbade Plaintiff from doing any further investigations of dissolution of Oxycodone HCI.
- Plaintiff advocated strongly for further testing in order to ensure that the drug, as it was being marketed and sold, was safe for public use
- 13 Plaintiff was told not to voice concerns about Oxycontin, since Defendant Purdue did not want problems with the FDA
- Oxycontin, is one of the most profitable, if not the most profitable, drugs for Defendant Purdue.
- 15. Defendant Purdue is facing several law suits that allege that patient addiction to Oxycodone HCl is through use of Oxycontin.
- 16 Plaintiff and his scientists also measured particle size of Oxycodone HCL which influences dissolution speeds of the chemical
- 17 Plaintiff discovered that the method for measuring particle sizes used at Purdue was not accurate

- 18 Plaintiff developed a new method to measure particle size and proposed new tighter particle size specifications as requested by the FDA.
  - 19 Smaller particles dissolve faster than bigger particles.
  - 20 Particle size needs to be controlled to control dissolution speed.
- 21. Variability in particle size of lots used in production may cause some of the lots to be dissolved faster than others potentially leading to overdose and addiction
- 22. After reporting his suggestions and conclusions that the company should adopt a tighter particle size specification as requested by the F D A., management refused to adopt those specifications and forbade Plaintiff from communicating with the regulatory department within the company
- Management also forbade Plaintiff from including in any written report his findings regarding different dissolution rates of different forms of Oxycodone
- At the International Research and Development meeting and various other meetings, Plaintiff announced that more testing was needed on Oxycodone to ensure its safety
  - 25 Management decided not to do any more testing on the drug
- 26 Management did not want any record of testing done on the drug that would have to be turned over to the FDA.
- 27. Management ignored FDA guidelines and Plaintiff's findings and adopted the position that the differences in dissolution rates in the drug were not significant
- 28 Management also ignored Plaintiff's report that there were possibly two different forms of Stearyl Alcohol used in production of Oxycontin that affected the

dissolution of Oxycontin.

- 29. Management ignored Plaintiff's report and ordered another report to be issued stating that there was only one form of Stearyl Alcohol present in the production material.
- 30 Management's position contravened FDA regulations including those under 65 Fed. Reg. 83,041 and 64 Fed. Reg. 65,716 which directs investigation of product safety, performance and efficacy in case another form of a drug substance having different dissolution properties was found.
- 31 In July 2002, as a result of Plaintiff voicing his concerns and speaking out about the need for additional testing. Defendant Purdue demoted Plaintiff.
- Defendant Purdue stripped him of his title and all of his supervisory responsibilities
  - 33. Defendant Purdue reduced his title to Senior Research Fellow.
- 34 As a pretext, Defendant Purdue alleged that Plaintiff was being demoted because he lacked adequate supervisory skills
- During the fall of 2002, Plaintiff continued to uncover additional information regarding the safety of Oxycontin.
  - 36 Purdue continually forbade him from detailing his findings in any report
- 37. In the fall of 2002, because of the intense pressure Purdue placed upon Plaintiff to keep his findings silent and not disclose any negative information, Plaintiff suffered serious physical problems
  - 38. Feeling the pressure to commit fraud and remain quiet, Plaintiff became

depressed and was forced to seek medical treatment and to take medication.

- 39. The work atmosphere became so intense and stressful, that Plaintiff suffered a severe heart attack in October 2002 and was hospitalized for six days and bedridden for another seven days.
- 40. Plaintiff is still recovering from the effects of the heart attack and has not been able to return to work since the heart attack
- 41 Plaintiff's heart pumping capacity is at 30% and consequently prevents him from walking at a normal pace.
  - 42. Plaintiff had a pace maker and a defibrillator implanted in him
- 43. He continues to suffer chest pains that prohibit him from performing all of his daily activities
- 44 In April 2003, Plaintiff informed the FDA of the potential safety problems with Oxycontin and the inadequacy of the testing being performed at Defendant Purdue
- 45 In May 2003, knowing that Plaintiff had complained to the FDA, Defendant Purdue fired Plaintiff for raising and voicing concerns about health risks associated with Oxycodone, one of Purdue's most profitable drugs
- 46. Although Defendant Purdue knew of Plaintiff's fragile psychological and physical health, Defendant Purdue caused Plaintiff emotional distress by terminating him unexpectedly and continuing to harass him by encouraging others to take credit for publications and reports that he generated.
- 47. Purdue has tried to diminish Plaintiff's scientific achievements which are a measure of his job adequacy, thus decreasing his ability to pursue other jobs in the

future

- 48. Because Plaintiff reported Defendant Purdue's illegal practices both internally and to the FDA, Defendant Purdue fired him
- 49. As a result of Defendant's Purdue's actions, Plaintiff suffered, and still suffers, serious physiological and psychologically effects.
- 50 Plaintiff was, and still is, being treated by a cardiologist and a psychiatrist. Plaintiff is still taking various medications for his mental and physical problems.
  - 51. By the above acts, Defendant Purdue violated C G S § 31-51m
- As a result of the Defendant's actions, Plaintiff has suffered, and continues 52 to suffer, financial damages and emotional distress

COUNT TWO: (Retaliation for Exercising Right of Free Speech-Violation of C.G.S. § 31-51q)

- 1-50. Paragraphs 1 through 50 of Count One are hereby made paragraphs 1 through 50 of this Count Two as if fully set forth
- 51 By their actions, stated herein above, Defendant Purdue violated C.G.S. § 31-51q
- 52. As a result of the Defendant's actions, Plaintiff has suffered, and continues to suffer, financial damages and emotional distress.

# COUNT THREE: (Common Law Wrongful Discharge)

- 1-50 Paragraphs 1 through 50 of Count One are hereby made paragraphs 1 through 50 of this Count Three as if fully set forth
- By their actions stated herein above, Defendant Purdue wrongfully terminated Plaintiff.

52. As a result of the Defendant's actions, Plaintiff has suffered, and continues to suffer, financial damages and emotional distress.

## COUNT FOUR: (Intentional Infliction of Emotional Distress)

- 1-50. Paragraphs 1 through 50 of Count One are hereby made paragraphs 1 through 50 of this Count Four as if fully set forth
- 51 By their actions stated herein above, Defendant Purdue intentionally inflicted emotional distress upon Plaintiff
- 52. As a result of the Defendant's actions, Plaintiff has suffered, and continues to suffer, financial damages and emotional distress.

### COUNT FIVE: (Negligent Infliction of Emotional Distress)

- 1-50. Paragraphs 1 through 50 of Count One are hereby made paragraphs 1 through 50 of this Count Five as if fully set forth.
- 51. By their actions stated herein above, Defendant Purdue negligently inflicted emotion distress upon Plaintiff.
- 52 As a result of the Defendant's actions, Plaintiff has suffered, and continues to suffer, financial damages and emotional distress.

## WHEREFORE, Plaintiff prays for:

- Compensatory damages; 1.
- 2 Punitive damages;
- Attorney's fees and costs of this action; 3
- 4 Interest; and
- 5 Such other relief as this Court deems necessary and proper

THE PLAINTIFF,

Victoria de Toledo, Esq Casper & de Toledo 1458 Bedford Street Stamford, CT 06905 Tel. No.: (203) 325-8600

Juris No. 106056

RETURN DATE: August 5, 2003

SUPERIOR COURT

MAREK ZAKRZEWSKI

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J D. OF DANBURY

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PURDUE PHARMA, L.P.

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### STATEMENT OF AMOUNT IN DEMAND

The Plaintiff claims damages in excess of \$15,000.00.

THE PLAINTIFF.

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